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IS 3390 (1988): Sphygmomanometers, Mercurial [MHD 13: Veterinary Hospital Planning and Surgical Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard
SPECIFICATION FOR
SPHYGMOMANOMETERS, MERCURIAL
(*Second Revision*)

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**AMENDMENT NO. 1 OCTOBER 1992
TO
IS 3390 : 1988 SPECIFICATION FOR
SPHYGMOMANOMETERS, MERCURIAL**

(Second Revision)

(Page 3, clause 4.2, third and fourth sentences) — Substitute the following for the existing sentences :

‘Rubber tubing shall have a minimum tensile strength and elongation at break before ageing as 105 kgf/cm² and 400 percent respectively. A reduction of 20 percent each shall be permitted on tensile strength and elongation after ageing.’

(Page 3, clause 4.8.3.2, informal table, against ‘Above 100 mm and below 200 mm’) — Substitute the following for the existing matter :

‘ Bag	+ 0
	-10

Cuff pocket	- 0
	+10

(Page 3, clause 4.8.3.2) — Insert the following note at the end :

‘NOTE — Within the deviations permitted above, the length and width of inflating bags shall be uniform throughout.’

(Page 3, clause 4.8.3.3) — Substitute the following for the existing clause :

‘4.8.3.3 The dimensions specified in 4.8.3.1 are overall dimensions. Seams in rubber bag, if provided shall be 4.0 ± 1.0 mm wide. Other dimensions may be permitted subject to agreement between the purchaser and the supplier.’

(Page 3, clause 4.8.4) :

a) *Line 9* — Substitute ‘3.5 ± 1 mm’ for ‘3 ± 0.5 mm’.

b) *Line 11* — Substitute ‘7.5 +1 mm’ for ‘8.0 mm’.

- 0

(*Page 5, clause 4.12*) — Insert the following sentence at the end of the clause:
'The error of a reading taken at any position on the scale shall be within ± 3 mm Hg.'

(*Page 5, clause 7.5, last sentence*) — Substitute the word 'show' for 'throw'.

Indian Standard

SPECIFICATION FOR SPHYGMOMANOMETERS, MERCURIAL

(*Second Revision*)

0. FOREWORD

0.1 This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards on 19 May 1988, after the draft finalized by the Anaesthetic Resuscitation and Allied Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard was first published in 1965. Its first revision came into existence in 1977 in which the improvement in the fastening device of the cuff and changes in some of the dimensions were carried out. However, in the second revision, an additional inclined type sphygmomanometer is added, requirement of the rubber for the rubber bag has been deleted, the requirements for the glass parts have been changed to clear glass and marking of 'On' and 'Off' on the tap provided in the reservoir are added. In the revised standard, instruction manual has also to be provided for the guidance of the consumers.

0.3 In the preparation of this standard, assistance

has been derived from the following:

IND/GS/MED 512 (b) Sphygmomanometer, armlet, rubber. Controllerate of Inspection General Stores, Ministry of Defence (DGI), Government of India.

BS 2744 : 1956 Sphygmomanometers, mercury type. British Standards Institution (BSI), UK.

GG-S-618(c) : 1960 Sphygmomanometer, aneroid and mercurial. Bureau of Federal Supply, Government Printing Office, USA.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Rules for rounding off numerical values (*revised*).

1. SCOPE

1.1 This standard lays down the requirements for mercurial sphygmomanometers used for measuring arterial blood pressure of human beings.

2. NOMENCLATURE

2.1 For the purpose of this standard, the nomenclature for various parts, as indicated in Fig. 1, shall apply.

3. TYPES, FASTENING AND SCALE RANGE

3.1 The sphygmomanometers shall be of the types, fastening and scale ranges as specified in 3.1.1 to 3.1.3.

3.1.1 Types

- a) Type 1 — Portable,
- b) Type 2 — Mountable/fixed, and
- c) Type 3 — Inclined.

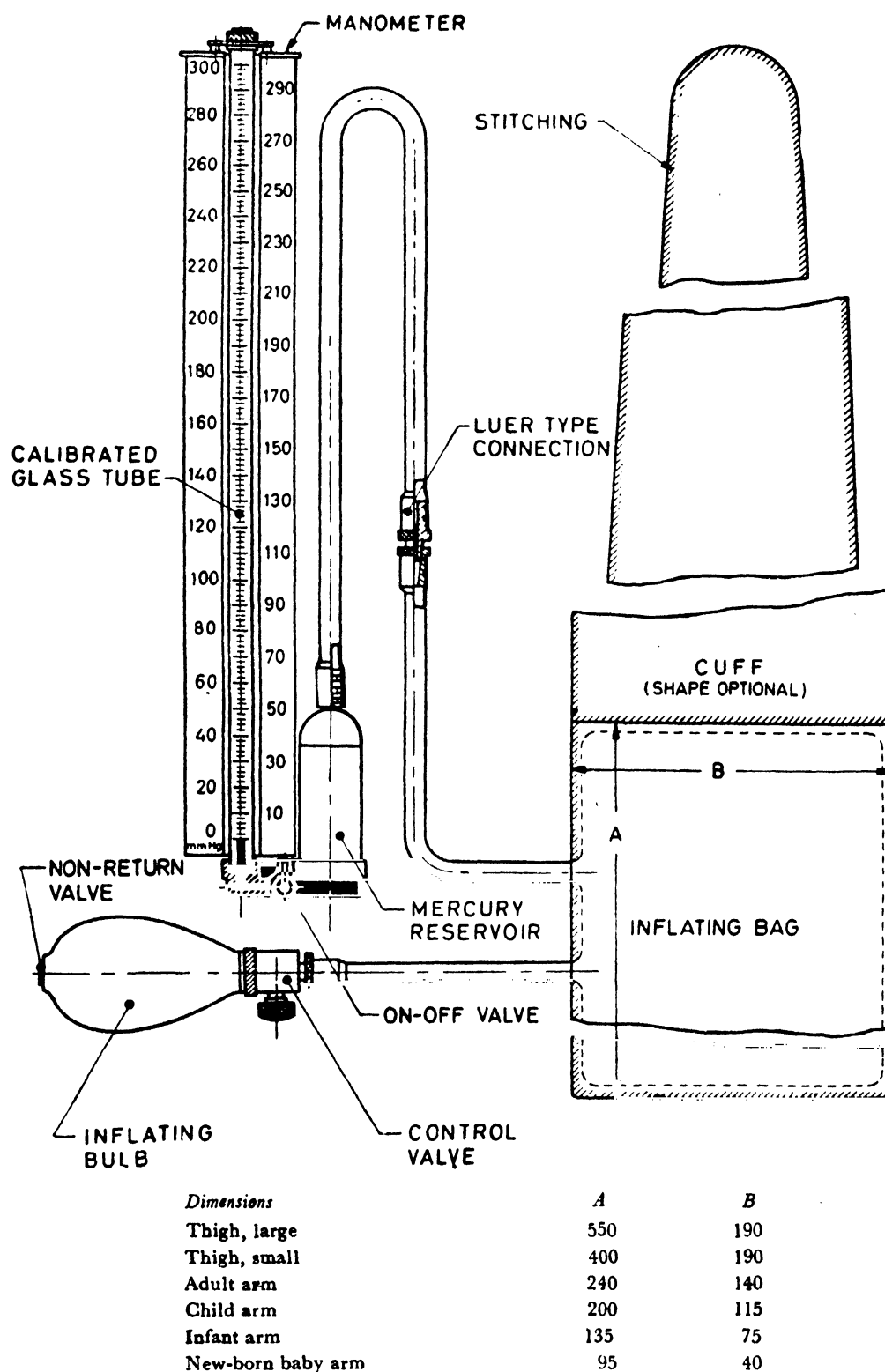
3.1.2 Fastening — The fastening arrangement of the cuff shall be such that the cuff should be capable of being held in position. The arrangement may be of bandage type, hook and rib type or any other convenient type. The fastening arrangement shall also satisfy the requirements given in 3.1.2.1.

3.1.2.1 The cuff shall be tied round a rigid cylinder of appropriate size and then pressurized to 50 mm (6.66 kN/m²), 200 mm (26.64 kN/m²), and 450 mm (59.94 kN/m²) of mercury in stages and kept at each stage for 3 minutes. There shall be no sign of slip or failure of cuff, stitching or the fastening arrangement.

3.1.3 Scale Range

Lower range : 0 mm of mercury

Upper range : 260 (34.66 kN/m²) to
300 (40.0 kN/m²)
mm of mercury



NOTE — Other dimensions may be permitted subject to agreement between the purchaser and the supplier.

All dimensions in millimetres.

FIG. 1 GENERAL ASSEMBLY OF SPHYGMOMANOMETER, MERCURIAL TYPE

4. MATERIAL

4.1 Metal Parts — The metal parts shall be fabricated from brass, aluminium alloy, steel or any other suitable metal intended. The metal parts shall be given a suitable corrosion resistant finish. If plating is done, it shall satisfy the corrosion resistance test specified in 7.5.

4.2 Rubber Parts — The rubber parts shall be made of natural or synthetic rubber. The inflating bulb, with its inlet valve in position, shall be capable of ageing in an air-oven for 168 h at $70 \pm 1^\circ\text{C}$ without showing appreciable stiffening, cracking or other change in condition. Rubber tubing shall have a minimum tensile strength and elongation at break before ageing as 105 kgf/cm² and 400 respectively. A reduction of 20 percent shall be permitted on tensile strength and 20 percent on elongation. The tensile strength and elongation shall be tested in accordance with IS : 3400 (Part 1)-1977*.

4.3 Glass Parts — The glass parts shall be made of clear glass. Glass shall show no evidence of corrosion, scumming, chipping or cracking, when subjected to the boil test as specified in 7.4.

4.4 Plastics — The plastics used shall be suitable for the purpose intended and shall not crack, flake, peel or otherwise disintegrate in normal use. The plastics tube shall remain clear like glass after subjecting to boil test as specified in 7.4.

4.5 Fabric — The fabric shall be of suitable cloth having minimum breaking load specified against variety No. 1 of IS : 178-1984†.

4.6 Sewing Thread — The sewing thread used shall be such that it satisfies the requirements given in 3.1.2.1.

4.7 Mercury — The mercury used shall be clean, double distilled and of 99.9 percent purity.

4.8 Component Part

4.8.1 Sphygmomanometers shall consist of an inflation system, a pressure measuring device (manometer), a housing for the manometer and its inflation system. These individual devices or replacement parts or complete sphygmomanometers may be ordered by the purchaser.

4.8.2 Inflation system shall consist of a cuff, inflating bag, inflating bulb and a control valve.

4.8.2.1 Cuff — The cuff shall be of the material specified in 4.5. Cuff shall be of two layers of material. A pocket shall be provided for the inflating bag made according to dimensions A and B (see Fig. 1). It shall have an opening of about 50 mm on the side for entry of inflating bag and to accommodate its tubes. The cuff shall be

long enough to give proper fastening to the required size of thigh or arm. The deviation on dimensions shall be as given in 4.8.3.2.

4.8.3 Inflating Bag — The inflating rubber bag shall be capable of withstanding an internal pressure of 450 mm of mercury without leaking, when tested as specified in 7.3.

4.8.3.1 The bag shall be of the following sizes:

	Length mm	Breadth mm
Large thigh	500	175
Small thigh	380	175
Adult arm	225	125
Child arm	180	100
Infant arm	120	60
New-born baby arm	80	25

4.8.3.2 Deviation as given below shall be applied on the dimensions given in 4.8.3.1 and Fig. 1:

		mm
Below 100 mm	Bag	+ 0 - 3
	Cuff pocket	- 0 + 3
Above 100 mm and below 200 mm	Bag	+ 0 - 5
	Cuff pocket	- 0 + 5
Above 200 mm	Bag	+ 0 - 10
	Cuff pocket	- 0 + 10

4.8.3.3 Other dimensions may be permitted subject to agreement between the purchaser and the supplier.

4.8.4 Tubing — Two lengths of rubber tubes, approximately 460 mm long each shall be attached to one long side of the bag and shall provide air entry from one end and exit from the other. These tubes shall be fitted with female Luer fittings conforming to IS : 3234-1979* to make leakproof connections with the male Luer fitting attached to the extension tubes. The internal diameter of the tubes shall be 3 ± 0.5 mm and external diameter shall be not less than 8.0 mm for fitting to inflating bags of child and adult sizes, and not less than 6.0 mm for infant sizes.

*Method of tests for vulcanized rubbers: Part 1 Tensile stress-strain properties (first revision).

†Specification for cotton twill (second revision).

*Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type (first revision).

4.8.5 Inflating Bulb — The inflating bulb shall be made of natural rubber or plastics and shall be avoid in shape. One end shall be securely fitted with an air inlet non-return valve. The other end shall be fitted over the proximal end of the control valve.

4.8.6 Control Valve — Control valve shall have a knurled thumb control device which shall be attached such that it does not become completely unscrewed. When the cuff is tied round a rigid cylinder of appropriate diameter, control valve shall be effective in holding a pressure of 300, 150 and 50 mm of mercury with a leakage rate not exceeding 10 mm of mercury per minute. The valve shall be tested at these points and at any intermediate points between 50 and 300 mm of mercury as may be deemed necessary to meet compliance (*see also 7.2*).

4.8.6.1 Control valve shall be capable of giving complete control by hand to give a reduction in pressure at the rate of 1 mmHg/s to free release.

4.8.6.2 One end of the control valve shall be attached to the inflating bulb and the other end to one of the tubes of the inflating bag.

4.9 Pressure Measuring Device

4.9.1 The manometers shall consist of a graduated glass tube, a reservoir, a connection from reservoir to manometer tube, a rubber tube extension with a male Luer fitting and sufficient mercury for proper operation of the instruments. The manometer tube shall be of adequate length for the purpose intended, and shall have an inside diameter of 4 ± 0.2 mm and wall thickness of not less than 2.0 mm. The manometer tube shall be calibrated and so designed in conjunction with the design of the remaining instrument as to be interchangeable, without calibration on the instruments of the same scale range of the same manufacturer. The scale markings and graduations shall be engraved and filled with pigment, etched and filled with pigment or accomplished by silk screening and fusing in or fusing on a pigment. The pigment shall be red, brown or black in colour and shall be permanent, meeting the requirements of boil test as given in 7.4. Any loss of pigment shall be a cause of rejection. The graduation shall extend from zero to full scale in 2-mm divisions with a proportionately longer markings at each 10-mm division on the tube. The longer divisions shall be about 30 to 40 percent longer than the shorter ones. The numerals shall be placed alternately on right and left side of the scale plate. The numerals on a scale plate may also be affixed in the back of the glass or plastics tube, if required by the purchaser. The colour, in which the numerals are marked, shall be in clear contrast to the background in order to be easily read. The pressure unit, that is, 'mmHg' shall be marked on the scale plate (*see 7.1 and 7.4*).

4.9.2 Tube Mounting and Fittings — The tube shall be recess-mounted to prevent breakage and shall provide a leak-proof channel for the mercury and shall be easily removable for cleaning and replacement. The upper end of the tube shall be fitted with a removable device containing a filter which shall prevent loss of mercury while still allowing the tube at all times to be open to atmospheric pressure and which shall also serve to prevent rapid oscillation and fluctuations of the mercury column, that is, damped column. This device shall be easily removable and replaceable to allow the addition of mercury, when necessary.

4.9.3 Reservoir and Connecting Tube — The reservoir, trap and connection to the manometer shall be made from suitable material, such as cast iron, steel or high impact resistant plastics, which shall have no deleterious effect on mercury. The reservoir shall be of uniform cross-section, its diameter shall be at least four times that of the manometer tube and its design shall be such as to allow interchangeability of the manometer tubes within instruments of the same scale range of the same manufacture. The reservoir shall be fitted with the safety trap at the top to prevent passage of mercury to the extension tube which will be fitted to the top of the reservoir making a leak-proof connection. The connection from reservoir to the manometer tube shall be air-tight, and mercury-tight, an 'On' and 'Off' tap shall be provided in the connection from the reservoir to the manometer tube.

4.9.4 Extension Tube — A rubber extension tube shall be fitted to the reservoir with a length not less than 300 mm and its end opposite to the reservoir shall be fitted with a male Luer fitting to make air-tight fit to the female Luer fitting fitted to one of the tubes of the inflating bag.

4.10 Housing — For Type 1, the case shall be of robust design and suitable material. It shall give ample room to house the inflation system without damage. It shall be fitted with a press-to-release lock which shall keep the case locked. The case shall be fitted with a device for setting and holding the lid at right angles. This device shall also prevent the accidental dropping of the lid when the instrument is in use. All parts shall be replaceable in case of breakage. The housing of the Type 2 shall be of wood or metal, and shall be of robust design.

4.11 Accessories — Besides an adult size cuff and inflating bag, the sphygmomanometers may be provided with one set of cuff and inflating bag of sizes specifically required by the purchaser. A cleaning brush to clean the manometer tube and a set of spare washers may be provided with each sphygmomanometer.

4.12 Accuracy — The assembled instrument shall be tested with the mercury column vertical for Type 1 and Type 2 and at the designed inclination for Type 3, and descending at an average rate of 2 mmHg approximately in 5 seconds, but the pressure shall be held constant while readings are being taken.

4.13 Leakage — The leakage of the completely assembled sphygmomanometer, when tested in accordance with 7.2, shall not exceed 10 mmHg per minute.

5. WORKMANSHIP AND FINISH

5.1 Workmanship shall be of high grade.

5.2 Sphygmomanometers shall be free from defects which detract from the appearance and may impair their serviceability.

6. MARKING

6.1 Each sphygmomanometer shall be legibly and permanently marked with the name or trade-mark of the manufacturer and the manufacturer's serial number.

6.1.1 The sphygmomanometers may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

7. TEST PROCEDURES

7.1 Calibration — All calibrations shall be accomplished with a properly standardized and certified mercurial manometer. One calibration shall be made without tapping and with decreasing pressure only. Reading shall be taken at the highest point of the scale and at all other points which are multiples of 20 mm. The readings shall be taken with the pressure falling at a rate of 2 mm/s approximately (*see 4.9.1*).

7.2 Leak Test — When the cuff of each completely assembled sphygmomanometer is tied round a rigid bar of appropriate diameter and each valve (when valves are purchased separately) shall be subjected to an internal air pressure of 50, 150 and 300 mmHg. The instrument or the valve shall then be cut off from the air supply. The leakage as given in 4.8.6 and 4.13 shall be permitted.

7.3 Leakage Test (Inflating Bag) — The bag shall be subjected to a pressure of 450 mmHg (gauge) for one minute. The bag shall be prevented from ballooning by the use of sufficient strength to withstand the pressure. There shall be no leakage (*see 4.8.2*).

7.4 Boil Test — The graduated tube shall be completely immersed in distilled water in a closed vessel having a steam vent and boiled continuously for six hours, boiling distilled water added when necessary to compensate for evaporation. The tube shall be suspended in water so that it does not come in contact with the containing vessel. The glass shall not show any evidence of corrosion, chipping or cracking and the graduations shall not have appreciably deteriorated in intensity (*see 4.9.1*).

7.5 Corrosion Resistance Test — The plated components shall be immersed in a 10 percent solution of citric acid at room temperature for 5 hours. They shall then be boiled in distilled water for 30 minutes and cooled while immersed in the same for 48 hours. The test shall be conducted in a glass container. The components shall throw no sign of corrosion.

8. PACKAGING

8.1 The sphygmomanometer shall be wrapped in a soft tissue paper and packed in a cardboard box or other equivalent box

9. INSTRUCTION MANUAL

9.1 Each sphygmomanometer shall be provided with a manual giving necessary instructions and precautions to be taken for its proper use. The instruction manual shall include technical specification of the sphygmomanometer, list of accessories and spare components to be supplied with the equipment.

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